REMARKS/ARGUMENTS

Claims 1-51 are in the case and presented for reconsideration. Claims 1, 12, 16, 35, 42 and 47 have been amended. No new matter has been added.

Claims 1-51 have been rejected under 35 U.S.C. §112, first paragraph. With respect to this rejection, the Examiner has stated:

> As related to claims 1, 12, 42 and 47, the specification does not disclose how the location of the minimum volume of the chamber of the heart is determined using the location of the non-contact electrodes and how it defines a cloud of space.
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> As related to claims 16 and 35, the specification does not disclose how the minimum volume of the heart chamber is determined using the location of the non-contact electrodes and how it defines a cloud of space.
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> Although the specification states on page 17 that this can be accomplished, it is unclear how it is accomplished, what equations are used and what minimum volume is actually being defined.

The Applicants respectfully traverse as follows. Applicants' Specification does indeed teach how the location of the minimum volume of the chamber of the heart is determined using the location of the non-contact electrodes and how it defines a cloud of space. For example, the Examiner's attention is directed to the Specification, Page 12, Lines 7-23, where it is clearly described that the catheter 20 of the system 18 in accordance with the present invention include a distal tip electrode 24, an array 23 of non-contact electrodes 25 and a location sensor 28. The location sensor 28 generates signals in response to externally applied magnetic fields which are generated by electromagnetic field generator coils 27 located near the patient. It is the magnitude of these signals generated by the location sensor 28 that depends on the position and orientation, i.e, the location, of the location sensor 28 in the applied magnetic field. In some embodiments according to the present invention, a second location sensor 48 (Fig. 3C) are used on the catheter 20 and positioned adjacent the proximal end 49 and the distal end 50 respectively of the array 23 of non-contact electrodes 25. Page 13, Lines 3-29.

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It is also clear from the Applicants' Specification that the various embodiments of the catheter 20 in accordance with the present invention have specific configurations for the array 23

of the plurality of non-contact electrodes 25. For example, the embodiment of Figs. 3A-3C comprises a total of sixteen point non-contact electrodes 25. And, that each non-contact electrode 25 has a circular cross-sectional share and a diameter of 1 mm. Moreover, the non-contact electrodes 25 of the array 23 are arranged in four columns spaced circumferentially around the catheter distal end in 90° increments. See Specification page 13, lines 8-17.

Furthermore, the Applicants' specification clearly explains that the position and/or orientation i.e., the location of non-contact electrodes 25 and 25a of array 23 and 23a respectively (alternative catheter embodiments in accordance with the present invention) are known in advance. And, "in order to know the location and orientation of each of the electrodes", the catheter in accordance with the present invention preferably employs two or more location sensors such as the location sensors 28 and 49 as shown in Fig. 3C. See Specification page 15, lines 1-8. Additionally, as specifically described in the Applicants' Specification on page 15, lines 8-13, at least one of the location sensors, i.e., either location sensor 28 or location sensor 48, provide six degrees of location and orientation information, i.e, three position coordinates (X, Y, and Z) and three orientation coordinates (pitch, roll and yaw).

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Additionally, the Applicants' specification is explicitly clear on how the position and orientation, i.e., the location of each of the non-contact electrode of the array are specifically determined. This is clearly described on page 15, lines 14-19 where it states:

> Fig. 6 shows the catheter distal end 22 in Fig. 3B in a deflected position. The orientation of sensors 28 and 49 may be characterized by lines 52 and 54, which represent the axes passing through sensors 28 and 49, respectively. Knowing the three-dimensional position and orientation of each of the sensors and the geometry of the electrodes 25 at the catheter distal end 22, the position and orientation of each of the electrodes 25 may be calculated, for example, using spline techniques.

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And, as noted by the Examiner, it is the location, i.e, the position and orientation, of the contact electrodes at each contact point that may be used to define a geometric map of the cardiac chamber. Thus, it is the totality of non-contact electrode locations, i.e., the position and orientation of each non-contact electrode (in accordance with six degrees of location and orientation information which includes X, Y and Z coordinates and pitch, roll and yaw

orientation coordinates) that are used to define the "cloud of space which represents a minimum chamber volume, i.e., in order to define the chamber geometry. As clearly stated, the location, i.e., the position and orientation of the non-contact electrodes may be used alone or in combination with the location, i.e., the position orientation of the contact electrodes at each of the contact points in order to define the geometry of the heart chamber. See specification, page 17, lines 17-23 and, of course, as outlined previously in the specification, for example, on page 15, lines 14-19 utilizing the known three-dimensional position and orientation of each of the location sensors and the known geometry of the non-contact electrodes, the position and orientation for each of the non-contact electrodes can be calculated, for example, using a method such as a splines technique. Accordingly, this rejection is believed to be without sufficient basis and should be withdrawn.

Claims 1-51 have been rejected under 35 USC §112 second paragraph, for being indefinite. The amendment made to claims 1, 12, 15, 35, 42 and 47 as outlined above are believed to have overcome this rejection.

Claims 1-3, 7, 9, 10, 12, 13, 15-18, 22, 24, 25, 32-37, 39-45, and 47-50 have been rejected under 35 USC §103(a) as being unpatentable over US Patent No. 5,718,241 (Ben-Haim) in view of US Patent No. 5,385,146 (Goldreyer). With respect to this rejection, the Examiner has stated:

> Ben Haim et al. disclose a method and apparatus to treat arrhythmias with ablation using one or more catheter (abstract). The tip of the catheter contains an electrode which can function at a site in the heart to sense electrical cardiac activity, to act as an antenna to deliver radio-frequency energy to perform ablation of tissue, or to deliver stimuli for pacing the heart (c 11, ll 28-35). The electromagnetic location system in the top of the catheter can contain between one and ten antennas to define the location of the tip area of the catheter (c 11,ll 49-59). In Figure 16, a tip electrode (105) and additional electrodes (106) are disclosed. The receiving antennas, located near the distal tip of the catheter (c 12, ll 41-47) provide location information for the local activation data received from the tip electrode (105) and additional electrodes (106) (c 7,ll 15-25; c 10, ll 33-45; claims 30 and 31). Ben-Ham et al. disclose the claimed invention except for:
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> The electrodes being non-contact electrodes linearly arranged along a longitudinal axis of the catheter body, and the location of the non-contact

electrode determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claims 1 and 2), determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contact electrode defines a cloud of space and determining a minimum volume of said heart chamber using the location of said non-contact electrodes (claims 16 and 35), at least one location sensor for determining a location of said contact electrode and location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 42) and at least one location sensor for determining a location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 48).

Goldreyer discloses a catheter to sense extremely localized intracardiac electrical patterns. As related to the non-contact electrodes arranged linearly, Figures 1 and 2 disclose a catheter (10/32) including a stimulating tip (14) and non-contact electrodes (34-46) shown to be 14 electrodes, read to be about a 16 electrodes (c 5, 11, 6-12). Goldreyer teaches an embodiment where the electrodes are non-contact (c 1, ll, 10-11) and are linearly arranged along a longitudinal axis of the catheter body to enable simultaneous sensing and ablation and/or pacing activity (c 1, 11, 55-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, and provide electrodes being non-contact electrode linearly arranged along a longitudinal axis of the catheter body as taught by Goldreyer to enable simultaneous sensing and ablation and/or pacing activity so accurate and discrete mapping of the electrophysiological activation with the heart is achieved (c 1, 1 63-, 2,14).

As related to the representation of the minimum volume of the heart chamber, Goldreyer teaches heart chamber mapping by sensing local cardiac signals in a minimal area of the heart chamber and repeating this process at predetermined positions with the chamber until accurate and discrete mapping of electrophysiological activation within the heart is achieved (c 1, 1 55-c 1, 1 ll,), hence the definition of the minimum volume of the heart chamber is accomplished by defining the location of the activation data within the heart chamber to a location sensor as disclosed by Ben-Haim et al. and by the predetermined position of the non-contact electrodes on the catheter as taught by Goldreyer (c 1, ll, 38-42 and 51-56 and c 3, ll, 53-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by Ben-Haim, and provide:

> The location of the non-contact electrode determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the art (claims 1 and 20, determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contact electrodes defines a cloud of space and determining a minimum volume of said heart chamber using the location of said non-contact electrode (claims 16 and 35), at least one location sensor for determining a location of said contact electrode and location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing minimum volume of the chamber of the heart (claim 42) and at least one location sensor for determining a location of said non-contact electrodes, the location of the non-contact electrodes determined by said at least one location sensor defining a cloud of space representing a minimum volume of the chamber of the heart (claim 48).
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> As taught by Goldreyer to enable accurate and discrete mapping of electrophysiological activation within the heart so optimal clinical treatment is provided to the patient (c 1, ll, 7-11).

Claims 4-6, 14, 19-21, 26-31, 38, 46 and 51 have been rejected under 35 USC §103(a) as being unpatentable over Ben-Haim et al. and Goldreyer in view of US Patent 6,104,944 (Martinelli). With respect to this rejection, the Examiner has sated:

> As discussed in paragraph 5 of this action, modified Ben-Haim et al. disclose the clamed invention except for providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array.
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> Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nm), read as location sensors in a proximate and a distal position relative to the electrode array.
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> Martinelli discloses a system and method for navigating a multiple electrode catheter and teaches that it is known to use two or more navigated electrode elements (N1-Nm), read as location sensors, between multiple virtually navigable electrode elements (El-En), read as an array of non-contact electrodes (column 4, line 66, column 5, line 8, and column 5, lines 24) to define the position of electrodes in a domain such as a chamber of the heart (column 4, lines 63-66). Martinelli teaches the use of electromagnetic field sensors as the navigate electrode elements to provide navigational location informational (column 6, lines 18-32). These navigated electrode elements provide orientation data and position coordinate data, read as the six degrees of location information

> (column 6, lines 54-64, and column 8, lines 29-65), to establish the location of the virtually navigated electrode and enable accurate mapping of the heart.
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> Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim, providing six degrees of location information using location sensors in a proximate and a distal position relative to the electrode array as taught by Martinelli to enable accurate mapping of the heart so arrhythmia producing cardiac tissue is identified and can be ablated.

Clams 8, 11, and 23 have been rejected under 35 USC §103(a) as being unpatentable over Ben-Haim and Goldreyer view of US Patent 6, 171,306 (Swanson). With respect to this rejection, the examiner has sated:

> As discussed in paragraph 5 of this action, modified Ben-Haim discloses the invention except for the distal tip contact electrode being bipolar electrode. Swanson et al. disclose an ablation catheter and teach that it is known to use a bipolar distal tip electrode to ablate the cardiac tissue (figure 5, column 7, lines 11-145). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus to treat arrhythmias with ablation as taught by modified Ben-Haim, with a bipolar distal tip electrode as taught by Swanson et al. to utilize the electrodes in the device, the tip and the array of electrodes, to ablate the tissue, eliminating the need for the addition of an external indifferent electrode (column 7, lines 17-32). Utilizing a bipolar configuration also provides a more targeted ablating stimulus enabling more precise ablation.

Turning now to the cited prior art references, the Applicants would like to outline the relevant teachings therefrom. Accordingly, Ben-Haim et al. discloses an apparatus and method for treating cardiac arrthmyias with no discrete target using a catheter 77 having receiving antenna 79 and a tip electrode 83. In another embodiment (Fig. 14), a catheter has a tip electrode 105 and additional electrode (106) ring electrode along with a receiving antenna 103. It is important to note that both of these catheter embodiments are directed toward determining lines or points of ablation such that an optimal line of points of ablation can be determined and created using energy delivered from the tip of the catheter for ablating heart tissue. It is also important to note that this reference does not in any manner describe an apparatus, catheter or method used to generate an electrical map of a heart chamber having the novel combination of features and method steps respectively such as found with the Applicants' claimed present

invention, And, it is neither described, suggested or even inferred in this reference to utilize at least one location sensor for generating signals in order to determine the location; i.e., the position and/or orientation, of an array of non-contact electrodes linearly arranged along the longitudinal axis of a catheter body such that the location, i.e., the position and orientation, of the non-contact electrodes (of the array) define a cloud of space which represents a minimum volume of the chamber geometry of the heart. Clearly, the Applicants' claimed invention as summarized above, is a rapid mapping apparatus, catheter and method simply not addressed, suggested or even inferred in Ben-Haim.

Moreover, Goldreyer is directed to orthogonal sensing for use in clinical electropsysiologlly using a catheter 10 incorporating a plurality of orthogonal sensing electrodes 12 and a stimulating tip 14. Although the Goldreyer catheter is used for mapping of electrophysiological activation within a heart, this reference is completely silent and does not address or even infer in any manner the possibility of utilizing at least one location sensor to determine the location; i.e., the position and orientation of an array of non-contact electrodes such that the location (position and orientation) of non-contact electrodes are used to define a cloud of space representing a minimum volume of the chamber geometry of the heart.

It is important to note that neither Ben-Ham et. al. nor Goldreyer, either alone or in combination with each other, describe, suggest, or infer these novel aspects of the Applicants' claimed present invention such as outlined above. Accordingly, any efforts to utilize these references in a manner that would possibly arrive at the Applicants' claimed invention could only be achieved by using Applicants' own specification and is a classic use of hindsight.

Martinelli is directed to a method and system for navigating a multiple electrode catheter and is outlined in the latest Office Action in paragraph 6. Although contrary to the Examiner's statement, the Applicant notes that the Martinelli system does not provide for six degrees of location information, but rather five degrees of location information (x, y, z and θ, ϕ).

Not claimed

Swanson et al. is directed toward systems and methods for forming large lesions in body tissue using curvilinear electrode elements. The Applicant would like to point out that the

Swanson et al. device is a flexible ablating element having a plurality of segmented electrodes comprised of "solid rings" pressure fitted about he body of the ablating elements.

Accordingly, neither Martinelli nor Swanson et al. describe, suggest, or infer the Applicant's claimed invention as outlined above. Moreover, even if one were to combine Martinelli and/or Swanson et al. in combination with Ben-Haim and Goldreyer, one of ordinary skill in this field would not be led to the Applicant's claimed invention without having to refer to the applicant's own specification in hindsight. Accordingly, by this Amendment and/or the reasons listed above, the Applicants' claimed present invention as amended is neither anticipated by nor rendered obvious by the cited prior art references and favorable action is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made".

By:____________________
Louis J. Capezzuto
Reg. No. 37,107

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2218
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In The Claims:

Claim 1. (Three Times Amended) A catheter for mapping a chamber of a heart comprising:

a body having a proximal end and a distal end, said distal end having a distal tip;

a contact electrode at said distal tip;

an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and

at least one location sensor on said distal end of said body for [determining] generating signals used to determine a location of said contact electrode and a location of said non-contact electrodes, the location of the non-contact electrodes determined by said signals generated by said at least one location sensor, said location of the non-contact electrodes defining a cloud of space representing a minimum volume of the chamber geometry of the heart.

Claim 12. (Three Times Amended) A catheter for mapping a chamber of the heart comprising:

a body having a proximal end and a distal end, said distal end having a distal tip;

an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and

at least one location sensor proximate to said distal tip for [determining] generating signals used to determine a location of said non-contact electrodes, the location of said non-contact electrodes determined by said signals generated by said at least one location sensor, said location of the non-contact electrodes defining a cloud of space representing a minimum volume of the chamber geometry of the heart.

Claim 16. (Three Times Amended) A method for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said method comprising the steps of:

a) providing a catheter comprising a body having a proximal end and a distal end, said distal end having a distal tip; a contact electrode at said distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor on said distal end of said body;

b) advancing said catheter into said chamber of said heart;

c) determining a location of said contact electrode and a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contact electrodes defines a cloud of space;

d) contacting a wall of said chamber of said heart with said contact electrode at a plurality of contact points;

e) acquiring electrical information and location information from each of said electrodes and said at least one location sensor, respectively, said acquisition taking place over at least one cardiac cycle while said contact electrode is in contact with each of said contact points; and

e) determining a minimum volume of said heart chamber <u>geometry</u> using the location of said non-contact electrodes;

f) generating an electrical map of said heart chamber from said acquired location and electrical information.

Claim 35. (Three Times Amended) A method for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said method comprising the steps of:

a) providing a catheter comprising a body having a proximal end and a distal end, said distal end having a distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-

contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor proximate to said catheter distal tip;

b) advancing said catheter into said chamber of said heart;

c) determining a location of said non-contact electrodes using said at least one location sensor wherein the location of said non-contact electrodes defines a cloud of space;

d) contacting a wall of said chamber of said heart with said catheter distal tip at a plurality of contact points;

e) acquiring electrical information and location information from each of said non-contact electrodes and said at least one location sensor, respectively, said acquisition taking place over at least one cardiac cycle while said catheter distal tip is in contact with each of said contact points;

f) determining a minimum volume of said heart chamber <u>geometry</u> using the location of the non-contact electrodes; and

g) generating an electrical map of said heart chamber from said acquired location and electrical information.

Claim 42. (Three Times Amended) Apparatus for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said apparatus comprising:

a catheter including a body having a proximal end and a distal end, said distal end having a distal tip; a contact electrode at said distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor on said distal end of said body for [determining] <u>generating signals used to</u> determine a location of said contact electrode and a location of said non-contact electrodes, the location of the non-contact electrodes determined by said <u>signals generated by</u> said at least one location <u>sensor, said location of the non-contact electrodes</u> defining a cloud of space representing a minimum volume of the chamber <u>geometry</u> of the heart; said catheter being adapted to contacting a wall of said chamber of said heart with said contact electrode at a

plurality of contact points; and a signal processor operatively connected to said catheter for acquiring electrical information and location information from each of said contact electrode and said non-contact electrodes and location sensors, respectively, over at least one cardiac cycle while said contact electrode is in contact with each of said contact points, said signal processor also generating an electrical map of said heart chamber from said acquired location and electrical information.

Claim 47. (Three Times Amended) Apparatus for generating an electrical map of a chamber of a heart, said map depicting an electrical characteristic of the chamber as a function of chamber geometry, said apparatus comprising:

a catheter including a body having a proximal end and a distal end, said distal end having a distal tip; an array of non-contact electrodes on said distal end of said body, said array having a proximal end and a distal end, wherein said non-contact electrodes are linearly arranged along a longitudinal axis of said body; and at least one location sensor proximate to said catheter distal tip for [determining] generating signals used to determine a location of said non-contact electrodes, the location of said non-contact electrodes determined by said signals generated by said at least one location sensor, said location of said non-contact electrodes defining a cloud of space representing a minimum volume of the chamber geometry of the heart; said catheter being adapted to contacting a wall of said chamber of said heart with said catheter distal tip at a plurality of contact points; and a signal processor for acquiring electrical information and location information from each of said electrodes and location sensors, respectively, over at least one cardiac cycle while said catheter distal tip is in contact with each of said contact points; said signal processor also generating an electrical map of said heart chamber from said acquired location and electrical information.